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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/357,273 | 07/20/99 | KAUFMAN R | UMV-1584 |

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HM22/0502

| EXAMINER | |
|---|---|
| KERR, J | |
| **ART UNIT** | **PAPER NUMBER** |
| 1633 | 12 |

**DATE MAILED:** 05/02/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/357,273 | Applicant(s) KAUFMAN ET AL. | |
|---|---|---|---|
| | Examiner Janet Kerr | Art Unit 1633 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-30 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 7, 11-16, and 27-29, drawn to a polynucleotide, and vectors and host cells comprising the polynucleotide, and methods of using the polynucleotide classified in class 536, subclass 23.1, 23.2 and 23.5, class 435, subclasses 69.1, 70.1, and 455, and class 514, subclass 44, for example.

II. Claims 6, and 17-19, drawn to a protein, classified in class 530, subclass 350, for example.

III. Claims 8-10, drawn to antibodies, classified in class 530, subclasses 387.1 and 388.1, for example.

IV. Claims 20-22, drawn to a cell comprising mutated hIre1p, classified in class 435, subclass 325, for example.

V. Claims 23-26, drawn to a probe and methods of use, classified in class 536, subclass 24.3, and class 435, subclass 6, for example.

VI. Claim 30, drawn to a method of increasing sensitivity of a cell to death comprising inhibiting the expression of hIRE1 in the cell, unclassifiable.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III and V are distinct, each from the other, as the products of the inventions are distinct structurally and functionally, and can be used in materially different processes. As examples, the polynucleotides of Invention I can be used to modulate cell viability, the proteins of Invention II can be used for antigen presentation, the antibodies of Invention III can be used in protein purification protocols, and the probes of Invention V can be used in hybridization screens. The differences among Inventions I-III and V are further underscored by their divergent classification and independent search status.

Invention I is distinct from Invention IV as the cells of the inventions are different, i.e., the cells of Invention I comprise a polynucleotide which encodes a protein having a particular

function whereas the cells of Invention IV comprise a mutated protein. The polynucleotide of claim I is not required for the production of the cells of Invention IV as there are other methods of creating cells comprising mutated proteins, e.g., by X-rays, UV irradiation and mutagenic compounds. The differences between Inventions I and IV are further underscored by their divergent classification and independent search status.

Invention I is distinct from Invention VI as the method of Invention I, directed to a method of increasing the survival of a cell, requires different technical considerations, and has different end results than that of the method of Invention VI, directed to increasing the sensitivity of a cell to death. The differences between Inventions I and VI are further underscored by their independent search status.

Invention II is distinct from Inventions IV-V as the protein of Invention II is distinct functionally and structurally from the mutated protein of Invention IV and the nucleic acid probes of Invention V. The differences between Invention II and Inventions IV-V are further underscored by their divergent classification and independent search status.

Invention II is distinct from Invention VI as the protein of Invention II is not required to reduce to practice the method of Invention VI. Furthermore, the protein of Invention II can be used in a materially different process, i.e., the protein of Invention II can be used for antigen presentation. The differences between Inventions II and VI are further underscored by their independent search status.

Invention III is distinct from Inventions IV-V as the antibodies of Invention III are structurally and functionally distinct from the cells of Invention IV and the nucleic acid probes of Invention V. Furthermore, the antibodies of Invention III can be used in a materially different process, i.e., the antibodies can be used in protein purification technologies. The differences between Invention III and Inventions IV-V are further underscored by their divergent classification and independent search status.

Invention III is distinct from Invention VI as the antibodies of Invention III are not required to reduce to practice the method of Invention VI, directed to increasing the sensitivity of

a cell to death. Furthermore, the antibodies of Invention III can be used in a materially different process, i.e., the antibodies can be used in protein purification technologies. The differences between Inventions III and VI are further underscored by their divergent classification and independent search status.

Invention IV is distinct from Invention V as the cells of Invention IV are different structurally and functionally from the probes of Invention V. Furthermore, the cells of Invention IV can be used in a materially different process, i.e., the cells can be used in methods of producing mutated hIre1p. The differences between Inventions IV and V are further underscored by their divergent classification and independent search status.

Invention IV is distinct from Invention VI as the cells of Invention IV are not required to reduce to practice the method of Invention VI, directed to increasing the sensitivity of a cell to death. Furthermore, the cells of Invention IV can be used in a materially different process, i.e., the cells can be used in methods of producing mutated hIre1p. The differences between Inventions IV and VI are further underscored by their divergent classification and independent search status.

Invention V is distinct from Invention VI as the methods of the Inventions require different starting materials, require different technical considerations, and have different end results. In addition, the nucleic acid probes of Invention V are not required to reduce to practice the method of Invention VI. The differences between Inventions V and VI are further underscored by their independent search status.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to Deborah Clark, Supervisory Primary Examiner of Art Unit 1633, at (703) 305-4051. Any administrative or procedural questions should be directed to Kimberly Davis, Patent Analyst, at (703) 305-3015. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Janet M. Kerr, Ph.D.
Patent Examiner
Group 1600

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SUPERVISORY PATENT EXAMINER
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